

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew McMichael, Adrian V.S. Hill, Sarah C. Gilbert, Jörg Schneider, Magdalena Plebanski, Tomas Hanke, Geoffrey L. Smith, and Tom Blanchard

Application No.: 10/686,943 Group Art Unit: 1648

Filed: October 16, 2003 Examiner: Louise Wang Zhiying Humphrey

Confirmation No.: 4585

METHODS AND REAGENTS FOR VACCINATION WHICH  
GENERATE A CD8 T CELL IMMUNE RESPONSE

CERTIFICATE OF MAILING OR TRANSMISSION

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Mary J. Dawson

Typed or printed name of person signing certificate

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

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(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)



Statement Under 37 CFR 1.97(e)

- [ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

[X] Copies of the cited references (AO-AQ and AV10-AS15) are enclosed.

[X] Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

[ ] Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

[ ] The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

[ ] The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

[ ] the enclosed English language abstract.

- [ ] Applicant requests that the following non-published pending applications be considered:  
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's  
Initials

- \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

Examiner

Date

- [ ] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.  
[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.  
[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.  
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Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: May 16, 2006

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 2907.1000-003	APPLICATION NO. 10/686,943
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  May 16, 2006  (Use several sheets if necessary)	FIRST NAMED INVENTOR Andrew McMichael	FILING DATE October 16, 2003
	EXAMINER Louise W. Z. Humphrey	CONFIRMATION NO. 4585
		GROUP 1648

## **U.S. PATENT DOCUMENTS**

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## **FOREIGN PATENT DOCUMENTS**

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AV10	Ahlers, J.D., <i>et al.</i> , "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-1 Vaccine Constructs," <i>The Journal of Immunology</i> , 158(8):3947-3958 (1997).
AW10	Allen, T.M. and Watkins, D.I., SIV and SHIV CTL Epitopes Identified in Macaques [online], December 1998. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/hiv-db/COMPENDIUM/1998/III/Allen98.pdf">http://hiv-web.lanl.gov/content/hiv-db/COMPENDIUM/1998/III/Allen98.pdf</a> >.
AX10	An, L.-L., and Whitton, J.L., "A Multivalent Minigene Vaccine, Containing B-Cell, Cytotoxic T-Lymphocyte, and T <sub>h</sub> Epitopes from Several Microbes, Induces Appropriate Responses In Vivo and Confers Protection against More than One Pathogen," <i>Journal of Virology</i> , 71(3): 2292-2302 (1997).
AY10	Austyn, J.M. and Wood, K.J., "An Overview of Immune Responses," In <i>Principles of Cellular and Molecular Immunology</i> , (NY: Oxford University Press Inc.), pp. 42-44 (1993).
AZ10	Bakker, A.B.H., <i>et al.</i> , "Identification of a Novel Peptide Derived from the Melanocyte-Specific GP100 Antigen as the Dominant Epitope Recognized by an HLA-A2.1-Restricted Anti-Melanoma CTL Line," <i>Int. J. Cancer</i> , 62: 97-102 (1995).
AR11	Bergmann, C.C., <i>et al.</i> , "Flanking Residues Alter Antigenicity and Immunogenicity of Multi-Unit CTL Epitopes," <i>The Journal of Immunology</i> , 157(8): 3242-3249 (1996).
AS11	Bukowski, J.F., <i>et al.</i> , "Natural Killer Cell Depletion Enhances Virus Synthesis and Virus-Induced Hepatitis In Vivo," <i>The Journal of Immunology</i> , 131(3): 1531-1538 (1983).
AT11	Casares, N., <i>et al.</i> , "CD4 <sup>+</sup> /CD25 <sup>+</sup> Regulatory Cells Inhibit Activation of Tumor-Primed CD4 <sup>+</sup> T Cells with IFN-γ-Dependent Antiangiogenic Activity, as well as Long-Lasting Tumor Immunity Elicited by Peptide Vaccination," <i>The Journal of Immunology</i> , 171(11): 5931-5939 (2003).
AU11	Cox, W.I., <i>et al.</i> , "Induction of Cytotoxic T Lymphocytes by Recombinant Canarypox (ALVAC) and Attenuated Vaccinia (NYVAC) Viruses Expressing the HIV-1 Envelope Glycoprotein," <i>Virology</i> , 195: 845-850 (1993).
AV11	Egan, M.A., <i>et al.</i> , "Use of Major Histocompatibility Complex Class I/Peptide/β2M Tetramers To Quantitate CD8 <sup>+</sup> Cytotoxic T Lymphocytes Specific for Dominant and Nondominant Viral Epitopes in Simian-Human Immunodeficiency Virus-Infected Rhesus Monkeys," <i>Journal of Virology</i> , 73(7): 5466-5472 (1999).
AW11	Eisenlohr, L.C., <i>et al.</i> , "Flanking Sequences Influence the Presentation of an Endogenously Synthesized Peptide to Cytotoxic T Lymphocytes," <i>The Journal of Experimental Medicine</i> , 175: 481-487 (1992).

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AX11	Feng, C.G., <i>et al.</i> , "Induction of CD8 <sup>+</sup> T-lymphocyte Responses to a Secreted Antigen of <i>Mycobacterium Tuberculosis</i> by an Attenuated Vaccinia Virus," <i>Immunology and Cell Biology</i> , 79: 569-575 (2001).
AY11	Gherardi, M.M., <i>et al.</i> , "Prime Boost Immunization Schedules Based on Influenza Virus and Vaccinia Virus Vectors Potentiate Cellular Immune Responses Against Human Immunodeficiency Virus Env Protein Systemically and in the Genitorectal Draining Lymph Nodes," <i>The Journal of Virology</i> , 77(12): 7048-7057 (2003).
AZ11	Gönczöl, E., <i>et al.</i> , "Preclinical Evaluation of an ALVAC (canarypox)-human Cytomegalovirus Glycoprotein B Vaccine Candidate," <i>Vaccine</i> , 13(12): 1080-1085 (1995).
AR12	HIV CTL Epitopes Table 2 p24. [online], December 1996. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/p24.pdf">http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/p24.pdf</a> >.
AS12	HIV CTL Epitopes Table 3: p24 [online], December 1999. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/immunology/pdf/1999/1/tablecs/p24.pdf">http://hiv-web.lanl.gov/content/immunology/pdf/1999/1/tablecs/p24.pdf</a> >.
AT12	HIV CTL Epitopes Table 4: Pol [online], December 1997. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/hiv-db/immunology/PDF/1997/CTL/tables/pol.pdf">http://hiv-web.lanl.gov/content/hiv-db/immunology/PDF/1997/CTL/tables/pol.pdf</a> >.
AU12	HIV CTL Epitopes Table 6 gp120. [online], December 1996. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp120.pdf">http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp120.pdf</a> >.
AV12	HIV CTL Epitopes Table 7 gp41. [online], December 1996. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp41.pdf">http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/gp41.pdf</a> >.
AW12	HIV CTL Epitopes Table 8 Nef. [online], December 1996. Retrieved from the Internet <URL: <a href="http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/nef.pdf">http://hiv-web.lanl.gov/content/immunology/pdf/1996/CTL/TABLES/nef.pdf</a> >.
AX12	Hu, S.-L., <i>et al.</i> , "Protection of Macaques Against SIV Infection by Subunit Vaccines of SIV Envelope Glycoprotein gp160," <i>Science</i> , 255: 456-459 (1992).
AY12	Hunter, C.A., "How are NK Cell Responses Regulated During Infection?," <i>Experimental Parasitology</i> , 84: 444-448 (1996).
AZ12	Janeway, C.A., <i>et al.</i> , "General Properties of Armed Effector T Cells," In <i>Immuno Biology</i> , (NY: Garland Publishing a member of the Taylor & Francis Group) p. 319 (2001).

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AR13	Konishi, E., <i>et al.</i> , "Induction of Japanese Encephalitis Virus-specific Cytotoxic T Lymphocytes in Humans by Poxvirus-based JE Vaccine Candidates," <i>Vaccine</i> , 16(8): 842-849 (1998).
AS13	Konishi, E., <i>et al.</i> , "Poxvirus-Based Japanese Encephalitis Vaccine Candidates Induce JE Virus-Specific CD8 <sup>+</sup> Cytotoxic T Lymphocytes in Mice," <i>Virology</i> , 227: 353-360 (1997).
AT13	Kuby, J., "Cell-Mediated and Humoral Effector Responses," In <i>Immunology</i> , (NY: W. H. Freeman and Company) pp. 379-412 (1997).
AU13	Linnemeyer, P.A., "The Immune System - An Overview," [online] November 1993 [retrieved on 2006-04-12]. Retrieved from the Internet <URL: <a href="http://www.thebody.com/step/immune.html">http://www.thebody.com/step/immune.html</a> >.
AV13	Malcherek, G., <i>et al.</i> , "Supermotifs Enable Natural Invariant Chain-derived Peptides to Interact with Many Major Histocompatibility Complex-Class II Molecules," <i>J. Exp. Med.</i> , 181: 527-536 (1995).
AW13	Martin, R.M. and Lew, A.M., "Is IgG2a a Good Th1 Marker in Mice?" <i>Immunology Today</i> , 19:49 (1998).
AX13	Müller, H.M., <i>et al.</i> , "Thrombospondin Related Anonymous Protein (TRAP) of <i>Plasmodium Falciparum</i> in Parasite-Host Cell Interactions," <i>Parassitologia</i> 35(Suppl.): 69-72 (1993).
AY13	Narvaiza, I., <i>et al.</i> , Intratumoral Coinjection of Two Adenoviruses, One Encoding the Chemokine IFN- $\gamma$ -Inducible Protein-10 and Another Encoding IL-12, Results in Marked Antitumoral Synergy," <i>The Journal of Immunology</i> , 164(6): 3112-3122 (2000).
AZ13	Ojcius, D. M., <i>et al.</i> , "Is Antigen Processing Guided by Major Histocompatibility Complex Molecules?," <i>FASEB J.</i> , 8: 974-978 (1994).
AR14	Okuda, K., <i>et al.</i> , "Induction of Potent Humoral and Cell-Mediated Immune Responses Following Direct Injection of DNA Encoding the HIV Type 1 <i>env</i> and <i>rev</i> Gene Products," <i>Aids Research and Human Retroviruses</i> , 11(8): 933-943 (1995).
AS14	Ramirez, J.C., <i>et al.</i> , "Biology of Attenuated Modified Vaccinia Virus Ankara Recombinant Vector in Mice: Virus Fate and Activation of B- and T-Cell Immune Responses in Comparison with the Western Reserve Strain and Advantages as a Vaccine," <i>Journal of Virology</i> , 74(2): 923-933 (2000).
AT14	Reusser, P., <i>et al.</i> , "Cytomegalovirus-Specific T-Cell Immunity in Recipients of Autologous Peripheral Blood Stem Cell or Bone Marrow Transplants," <i>Blood</i> , 89(10): 3873-3879 (1997).

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AU14	Romero, P., <i>et al.</i> , "Cloned Cytotoxic T Cells Recognize an Epitope in the Circumsporozoite Protein and Protect Against Malaria," <i>Nature</i> , 341: 323-326 (1989).	
AV14	Takada, K., <i>et al.</i> , "Definition of an Epitope on Japanese Encephalitis Virus (JEV) Envelope Protein Recognized by JEV-specific Murine CD8+ Cytotoxic T Lymphocytes," <i>Arch Virol.</i> , 145: 523-534 (2000).	
AW14	Vasmatzis, G., <i>et al.</i> , "Computational Determination of Side Chain Specificity for Pockets in Class I MHC Molecules," <i>Molecular Immunology</i> , 33(16): 1231-1239 (1996).	
AX14	Whitton, J.L., <i>et al.</i> , "A "String-of-Beads" Vaccine, Comprising Linked Minigenes, Confers Protection from Lethal-Dose Virus Challenge," <i>Journal of Virology</i> , 67(1): 348-352 (1993).	
AY14	Yang, Y., <i>et al.</i> , "Upregulation of Class I Major Histocompatibility Complex Antigens by Interferon $\gamma$ is Necessary for T-cell-mediated Elimination of Recombinant Adenovirus-infected Hepatocytes <i>In Vivo</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 92: 7257-7261 (1995).	
AZ14	Yellen-Shaw, A.J., <i>et al.</i> , "Point Mutation Flanking a CTL Epitope Ablates In Vitro and In Vivo Recognition of a Full-Length Viral Protein," <i>The Journal of Immunology</i> , 158(7): 3227-3234 (1997).	
AR15	Zhu, M., <i>et al.</i> , "Specific Cytolytic T-Cell Responses to Human CEA from Patients Immunized with Recombinant Avipox-CEA Vaccine," <i>Clinical Cancer Research</i> , 6: 24-33 (2000).	
AS15	Thomson, S.A., <i>et al.</i> , "Recombinant Polyepitope Vaccines for the Delivery of Multiple CD8 Cytotoxic T Cell Epitopes," <i>J. Immunol.</i> , 157(2):822-826 (1996).	

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